

December 21, 2006

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Biopesticides and Pollution Prevention Division
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Ms. Linda Hollis

Subject: Application for Section 3 Registration
AFxRD-038 (EPA Registration Number 71297-XX)
Petition for Exemption From the Requirements for a Tolerance
Active Ingredient = 1-Methylcyclopropene (1-MCP)

AgroFresh, Inc., a wholly owned subsidiary of Rohm and Haas Company, submits an application for a Section 3 registration for the product AFxRD-038, a powder formulation containing 3.8% of the active ingredient 1-methylcyclopropene (1-MCP). AFxRD-038 is a formulated product produced from the EPA registered Manufacturing Use Product – SF, (EPA Registration No. 71297-4). This new formulation has been developed for pre-harvest use.

Also included with this submission is a petition to extend the exemption of 1-MCP from the requirements of a tolerance. The EPA has previously established an exemption from tolerance for fruits and vegetables for 1-MCP in post-harvest use. This petition proposes to extend the tolerance exemption to cover outdoor use of AFxRD-038 on the following commodities: pome fruit (Crop Group 11), kiwifruit, walnuts, fruiting vegetables, (Crop Group 8), corn, cotton, soybean and sunflower.

The formulation is packaged in water soluble pouches and then packed in sealed foil outer packages. The active ingredient, 1-MCP, is classified by EPA as a plant growth regulator structurally similar to ethylene and other naturally occurring plant materials and is regulated by the Biopesticide and Pollution Prevention Division.

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The Signal Word proposed for AFxRD-038 is CAUTION based on the results of acute toxicity testing submitted with this application and the results demonstrated with similar formulations of 1-MCP. Included with this cover letter is a proposed master label with three sublabels as well as the required product specific studies in triplicate. Additional administrative materials submitted with this letter are as follows:

1. Application Form (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Certification with Respect to Citation of Data (EPA Form 8570-34)
4. Data Matrix (EPA Form 8570-35) for New Submissions including blacked-out publicly releasable version
5. Data Matrix (EPA Form 8570-35) for Previously Submitted studies
6. Proposed Master Label for AFxRD-038 with three sublabels (5 copies)
7. Tolerance Exemption petition (3 copies)

The Formulator's Exemption Statement (EPA Form 8570-27) is not required because the active ingredient, 1-methylcyclopropene, is synthesized in an *in situ* process during the manufacture of AFxRD-038 by AgroFresh, Inc.

Based on the Federal Register Noticed issued on June 2, 2005 in Volume 70, no. 105, this submission falls under EPA # B67 because it is a new biochemical pesticide whose active ingredient is regulated by the Biopesticide and Pollution Prevention Division. The estimated registration fee is \$4200. In looking at the Biopesticides and Pollution Prevention Division Fee Categories, drafted March, 2004, the best fit category is EPA #B63 (\$10,500 from June, 2005 reference). Based on the more recent date of these two references, we believe this submission falls under EPA #B67.

Please assign MRID numbers to the newly submitted studies listed on the attachment and return the completed attachment to me. Also, please contact me if you have any questions regarding this submission. I can be reached by phone at 215-619-5534, fax at 215-619-1672 or email at abeaulieu@agrofresh.com. Thank you.

Sincerely,



Ann Beaulieu, Ph.D.
Director, Regulatory Affairs

Attachment

cc: Driss Benmhend

Guideline Reference Number	Report Number	Report Title	MRID
40 CFR 160.105	AF-06-073	Analysis of Pure cis2Butene and Assignment of Purity: Aldrich Batch #11620DE	Reject (01)
830.1700	AF-06-083	GLP Characterization of Five Representative Lots of AFxRD-038 Formulation	Reject (02)
830.6303, 6303, and 6304	AF-05-032	Determination of Colour, Physical State and Odour of AFxRD-038	Reject (03)
830.6313 and 6320	AF-06-077	Accelerated Storage Stability of 1-Methylcyclopropene Formulation AFxRD-038	Reject (04)
830.7000	AF-05-033	pH-Determination of an Aqueous Solution of AFxRD-038	Reject (05)
830.7050	AF-05-034	Determination of the UV/VIS Absorption Spectrum of AFxRD-038	Reject (06)
830.7050	AF-01-186	Determination of the UV/VIS Absorption Spectra of 1-MCP	47024907
830.7200 and 7220	AF-05-036	Determination of the Melting Point/Melting Range and the Boiling Point/Boiling Range of AFxRD-038	Reject (08)
830.7300	AF-05-035	Determination of the Bulk Density of AFxRD-038	Reject (09)
830.7520	AF-05-037	Determination of the Particle Size Distribution of AFxRD-038	Reject (10)
830.7860	AF-06-031	Determination of the Water Solubility of AFxRD-038,	Reject (11)
835.3110	01RC-0006	1-Methylcyclopropene (1-MCP): An Evaluation of Ready Biodegradability Using the Die-Away Test Method	47024912
850.1010	05RC-069	AFxRD-038: A 48-Hour Static Acute Immobilization Test with the Cladoceran (<i>Daphnia magna</i>),	Reject (13)
850.1010	01RC-0002	1-Methylcyclopropene: A 48-Hour Static Acute Immobilization Test with the Cladoceran (<i>Daphnia magna</i>)	47024914
850.1075	01RC-0001	1-Methylcyclopropene: A 96-Hour Static-Renewal Acute Toxicity test with the Rainbow Trout (<i>Oncorhynchus mykiss</i>)	47024915
850.1075	05RC-068	AFxRD-038: A 96-Hour Static-Renewal Acute Toxicity Test with the Rainbow Trout (<i>Oncorhynchus mykiss</i>),	Reject (16)
850.2100	05RC-071	AFxRD-038: An Acute Oral Toxicity Study with the Northern Bobwhite,	47024917
850.2200	05RC-072	AFxRD-038: A Dietary LC50 Study with the Northern Bobwhite	47024918
850.2200	06RC-130	AFxRD-038: A Dietary LC50 Study with the Mallard	47024919

Attachment

Guideline Reference Number	Report Number	Report Title	MRID
850.3020	01RC-0097	1-Methylcyclopropene Alpha-Cyclodextrin Complex (3.3% A.I.): An Acute Toxicity Study with the Honey Bee	47024920
850.4225	06R-1052	1-Methylcyclopropene: Rationale for Waiver of OPPTS 850.4225 Seedling Emergence	47024921
850.4250	06R-1053	1-Methylcyclopropene: Rationale for Waiver of OPPTS 850.4250 Vegetative Vigor	47024922
850.5400	05RC-070	AFxRD-038: A 96-Hour Toxicity Test with the Freshwater Alga (<i>Pseudokirchneriella Subcapitata</i>)	47024923
850.5400	01RC-0003	1-Methylcyclopropene: A 96-Hour Toxicity Test with the Freshwater Alga	47024924
860.1300	AF-06-079	¹⁴ C-1-Methylcyclopropene: Residues in Maize	Reject (25)
860.1300	AF-06-084	Environmental Fate of 1-MCP when Applied Pre-Harvest to Tomato Plants	Reject (26)
860.1300	AF-06-080	¹⁴ C-1-Methylcyclopropene: Residue in Apple	Reject (27)
870.1100	05RC-064	AFxRD-038: Acute Oral Toxicity Up and Down Procedure in Rats	47024928
870.1200	05RC-065	AFxRD-038: Acute Dermal Toxicity Study in Rats – Limit Test	47024929
870.2400	05RC-067	AFxRD-038: Primary Eye Irritation Study in Rabbits	47024930
870.2500	05RC-066	AFxRD-038: Primary Skin Irritation Study in Rabbits	47024931
Not Applicable	06-R-1048	Dermal Sensitization Potential of AFxRD-038: Rationale to Use Surrogate Toxicology Data	47024932
Not applicable	06R-1011	Acute Inhalation Potential of AFxRD-038: Rationale to Use Surrogate Toxicology Data	47024933
Not applicable	00R-183B	1-Methylcyclopropene Two-Week Inhalation Range-Finding Study in Male Rats	47024934
OECD 104	AF-06-001	Calculation of the Vapour Pressure of AFxRD-038	Reject (35)
OECD 104	AF-01-190	Determination of the Vapour Pressure of 1-MCP	Reject (36)
OECD 105	AF-01-191	Determination of the Water Solubility of 1-MCP	Reject (37)
OECD 111	AF-01-188	Hydrolysis Determination of 1-MCP at Different pH Values	47024938
OECD 312	AF-06-081	¹⁴ C-1-Methylcyclopropene: Leaching in Four Soils	Reject (39)
OECD 417	01R-004E	¹⁴ C-1-Methylcyclopropene: Toxicokinetic Study in Rats	Reject (40)

Attachment

Guideline Reference Number	Report Number	Report Title	MRID
Not Applicable	01RC-0283	1-Methylcyclopropene: Toxicity Test with the Parasitic Wasp, <i>Aphidius Rhopalosiphii</i> (Hymenoptera: Braconidae)	47024941
Not Applicable	AF-01-153	Determination of the Flammability of 1-MCP Formulation	47024942
Not Applicable	01RC-0282	1-Methylcyclopropene: Laboratory Toxicity Test with the Predatory Mite, <i>Typhlodromus Pyri</i> Scheuten (Acari: Phytoseiidae)	Reject (43)
Not Applicable	01RC-0284	1-Methylcyclopropene: A 14-Day Acute Toxicity Test with the Earthworm <i>Eisenia Fetida</i>	47024944
Group A – Product Chemistry	AF-06-010	Product Chemistry AFxRD-038 Formulation	Reject (45)
Not applicable	06-RC-193	AFxRD-038: Laboratory Acute Toxicity Test with the Parasitic Wasp, <i>Aphidius Rhopalosiphii</i> (Hymenoptera: Braconidae)	47024946
Not applicable	06RC-195	AFxRD-038: Laboratory Acute Toxicity Test with <i>Peocilus Cupreus</i> L. (Coleoptera: Carabidae)	47024947
Not Applicable	05R-1088	1-Methylcyclopropene: Structure-Activity Hazard Identification Screen Using DEREK	Reject (48)
Not applicable	06R-1056	Pre-harvest Use of 1-Methylcyclopropene on Agricultural Crops: Environmental Risk Assessment	47024949
Not Applicable	06R-1050	1-Methylcyclopropene: Rationale for Waiver of OPPTS 880.3550 Immunotoxicity	47024950
Not Applicable	01RC-1017	Atmospheric Fate of 1-Methylcyclopropene	Reject (51)
Not Applicable	01RC-1016	A laser Photolysis – Laser Induced Fluorescence Determination of the Rate Coefficient for the Reaction of the Hydroxyl Radical with 1-Methylcyclopropene	Reject (52)
Not applicable	AF-06-078	GLP Validation of the GC/FID Method for the Determination of 1-MCP in SmartFresh™ and AFxRD-038 Formulations using cis-2-Butene as a Calibration/Internal Standard	Reject (53)
Not applicable	06-R-1055	Pre-Harvest Use of 1-Methylcyclopropene on Agricultural Crops: Toxicology Summary and Assessment of Worker, Bystander and Consumer Risks	47024954